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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,882	02/11/2004	Valeri V. Golovlev	59004.US	3388
408	7590	12/09/2005	EXAMINER	
LUEDEKA, NEELY & GRAHAM, P.C.			DO, PENSEE T	
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KNOXVILLE, TN 37901			PAPER NUMBER	

1641

DATE MAILED: 12/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/776,882	Applicant(s) GOLOVLEV ET AL.	
	Examiner Pensee T. Do	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry & Claim Status

The amendment filed on June 22, 2005 has been acknowledged and entered.

Claims 1-14 and new claims 15-21 are pending.

Rejection(s) Withdrawn

Rejection under 112, 1st paragraph in the previous office action is withdrawn herein.

Some of the rejections under 112, 2nd paragraph in the previous office action are withdrawn herein.

Maintained Rejection(s)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for reciting "the particle ...is capable of electrostatic interaction with the solid support and the molecular structures". How can the particle interact with two different reagents, solid support and the molecular structures while it has only one kind of charge? Are the molecular structures coated on the solid support? If so, to which reagent, the molecular structures or the solid support, does the colloidal particle bind to?

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Claim 11 is indefinite of where the molecular structures are, on the solid support? Or stand-alone? See also claim 1 for the same issue.

New Grounds of Rejection

Claims 1-12, 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 11 and 12 recite "the substrate" which lacks antecedent basis.

Claim 12, line 10, "ones" seems to be a mistype. Please correct.

Claim 12, line 10, the "phrase which second agent when bound to the surface inhibits ones of the colloidal particles ***second agent bound thereto...***" is indefinite and confusing. It is unclear of what the role of "the second agent bound thereto" is with the regards to the inhibition of the colloidal particles.

Claim 14, the step of "providing...", is missing a word after "the screen".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Remacle et al. (USPGPub. No. US 2003/0096321 A1).

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Remacle teaches a method comprising providing a solid support having a surface, immobilizing probe molecular structures in multiple discrete regions on the surface, binding the probe molecular structures to the target the molecular structures in a sample; and precipitating colloidal particles on the surface of the solid support and capturing an image of diffusely reflected light from the surface of the solid support/surface. [0019], [0041], [0051], [0068]. For claim 15, Remacle teaches using a light absorbing screening at a predetermined distance behind the transparent support. (see fig. 2A-B, character 4 and 5- black and white screens). For claims 15, Remacle teaches that said sample substrate is preferably a transparent polymeric or glass slide and said support is configured for allowing the introduction of the sample into the opening bay of the device. [0086]. For claim 16, the substrate can be made from plastic [0045], which is inherently opaque.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 11, 12, 18, 19, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Remacle et al. (US Patent Application Publication 2003/0096321 A1) in view of Fritzsche et al. (Biomedical Nanotechnology Architecture and Applications, Vol. 4626, 2002).

Remacle teaches a method for the identification and/or quantification of a target compound obtained from a biological sample, comprising the steps of putting into contact the target compound with a capture molecule in order to allow a specific binding between said target compound and the capture molecule, said capture molecule being fixed upon a surface of a solid support according to an array comprising a density of at least 20 discrete regions per squared centimeter, each of said discrete region is fixed with a capture molecule, performing a reaction leading to a metallic precipitate (metal deposit) formed at the location of said binding, determining possible presence of the precipitate in discrete regions by the detection and recording means such as a scanner, and correlating the presence of the metallic precipitates at the discrete regions (precipitate pattern) with the identification and/or quantification of said target compound. [0019]. The solid support is made of glass, electronic device, polymeric or metallic materials, etc, including materials such as plastic supports, which present an intrinsic fluorescence. [0037]. The formation of a metallic precipitate at the location of binding is obtained with the fixation of a metallic compound upon the target compound or by the result of a metal precipitation in the presence of an enzyme. Advantageously, a reduction of silver in the presence of colloidal gold allows the formation of a precipitate. [0041], [0051]. The gold particles and the silver compound are in solution because Remacle teaches that the method is particularly well adapted for high throughput screening on microarrays using multiwell plates containing the solutions for performing the various steps of the process [0103- lines 18-21] The target and the capture molecules are DNA which

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can hybridize, [0052], [0055], or proteins [0049]. The gold colloidal particles have size from 1 μm to 20 μm in diameter. [0062]. Remacle also teaches a method for imaging a sample (said solid support surface comprising said metallic precipitation) comprising projecting a transmission mode light from a light source onto said sample during a transmission mode time period, detecting light on detector from the light source and projecting diffuse scattering light from the same light source onto said sample during similar or other than said reflection mode time period and detecting reemitted light on said detector from said sample. [0068]. The device for imaging a sample comprises a carrier element for supporting a sample. For claims 18 and 19, Remacle teaches that said sample substrate is preferably a transparent polymeric or glass slide and said support is configured for allowing the introduction of the sample into the opening bay of the device. [0086]. For claim 19, the substrate can be made from plastic [0045], which is inherently opaque. For claim 21, Remacle teaches a light absorbing screen which is located at a predetermined distance behind the substrate (see fig. 2A-2B, character 4 and 5 which are the black and white backgrounds). Gold particles are generally negatively charged. Thus, it is inherent that the gold colloidal particles used in Remacle are negatively charged.

With regards to claims 11 and 12, Remacle teaches incubating the array with anti-biotin conjugate coupled colloidal gold in a blocking buffer (100 mM maleic buffer pH 7.5, 150 mM NaCl and 0.1 % milk powder) which is equivalent to the second agent of the present invention (since the specification describes that the second agent is a blocker-see page 14, line 5-10 of the present specification).

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The blocker binds to the surface of the solid support and blocks binding of non-specific binding including the binding of the gold particles to the solid support.

[0136].

However, Remacle fails to teach measuring the density of the precipitated colloidal particles on the surface of the substrate.

Fritzsche teaches a method of nanoparticle-labeling technique from microscopical applications for DNA-chip detection. The method comprises binding a probe DNA to a solid support/ glass substrate in multiple sites, adding gold nanoparticle-labeled target DNA to the solid support/glass substrate; precipitating silver solution on the solid support; scanning the solid support and measuring the density of the nanoparticles based on the signal obtained. Strong signal means high density, and weak signal means low density. (see pages 18, 19, Results and discussion; 20).

It would have been obvious to one of ordinary skills in the art to measure the density of the nanoparticles at various locations on the solid support as taught by Fritzsche using the method of Remacle because both references teach imaging microarray using a scanner such as CCD. According to the method of measuring the density taught by Fritzsche, if the signal at a particular discrete site is strong, then the density of nanoparticle at such spot would be high and could be visualized by the naked eye and vice versa. Thus, one of ordinary skills in the art would be able to identify the location of the target on the solid support quickly without using any special device.

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Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Remacle in view of Fritzsche as applied to claim 1 above, and further in view of WO 95/22639.

WO 95/22639 teaches a process for producing coated, especially metal-coated, polymer particles, in which polymer microparticles with an electrically and preferably positively charged surface are synthesized and are then caused to react with oppositely charged, preferably metal-sol particles. (see abstract).

It would have been obvious to one of ordinary skills in the art to coat the negatively charged gold-metal particles with a positively charged polymer as taught by WO95/22639 and used such particles in the combined method of Remacle and Fritzsche because polymer coating provides functional groups which can bind to the solid support or the target biological substance.

Claims 8, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Remacle in view of Fritzsche as applied to claim 1 above, and further in view of Rubner et al. (US 5,536,573).

Remacle and Fritzsche have been discussed above.

However, Remacle and Fritzsche fail to teach treating the surface of the solid support with a solution of positively or negatively charged polymer substances.

Rubner teaches a method of treating the surface of a hydrophilic or hydrophobic glass slide by first immersing the substrate/solid support in the polycation solution and then in the polyanion solution to produce a negatively charged solid support. For a positively charged glass slide, the substrates were

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first immersed in the polyanion solution and then in the polycation solution. (see col. 11, lines 10-20).

It would have been obvious to one of ordinary skills in the art to use the method of surface treatment of the solid support/glass slide to produce positively or negatively charged glass slides as taught by Rubner to treat the solid support used in the method of Remacle and Fritzsche so that DNA molecules or proteins which contain an electrical charged can be absorbed on the solid support through electrostatic interaction.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Remacle in view of Fritzsche as applied to claim 1 above, and further in view of Roninson (US 4,675,283).

Remacle and Fritzsche fail to teach providing a latent pattern of molecular structures on the solid support by enzymatic digestion of molecular structures on the surface of the solid support.

Roninson teaches enzyme digestion to digest unhybridized single-stranded DNA and followed by detection. (see abstract).

Since DNA digestion is well known in the art to eliminate unhybridized single stranded DNA, it would have been obvious to one of ordinary skills in the art to use enzyme digestion to get eliminate unhybridized single stranded DNA as taught by Roninson to eliminate the unhybridized DNA in the method of Remacle and Fritzsche since Remacle and Fritzsche teach hybridizing DNA or nucleic acid on a solid substrate.

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Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Remacle in view of Caskey et al. (US 6,286,965).

Remacle has been discussed above.

However, Remacle fails to teach that the glass transparent substrate is blackened on one side by light absorbing paint.

It is well known in the art, as taught by Caskey, that light absorbing black paint is usually coated onto glass on one side to absorb most of the light transmitted through the mirror. (see col. 11, lines 46-60).

It would have been obvious to one of ordinary skills in the art to apply the same concept of painting one side of a glass substrate black as taught by Caskey in the method of Remacle for good quantification of the signal. Light, if not absorbed would reflect from the glass substrate. Thus, by using such a technique for absorbing light as taught by Caskey, all the light would be absorbed on the glass substrate and such absorption allows good quantification of the signal. (see Remacle col. 13, [0172]).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Remacle in view of Fritzsche as applied to claim 1 above, and further in view of Caskey (US 6,286,965).

Remacle and Fritzsche have been discussed above.

However, Remacle and Fritzsche fail to teach that the glass transparent substrate is blackened on one side by light absorbing paint.

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It is well known in the art, as taught by Caskey, that light absorbing black paint is usually coated onto glass on one side to absorb most of the light transmitted through the mirror. (see col. 11, lines 46-60).

It would have been obvious to one of ordinary skills in the art to apply the same concept of painting one side of a glass substrate black as taught by Caskey in the method of Remacle and Fritzsche for good quantification of the signal. Light, if not absorbed would reflect from the glass substrate. Thus, by using such a technique for absorbing light as taught by Caskey, all the light would be absorbed on the glass substrate and such absorption allows good quantification of the signal. (see Remacle col. 13, [0172]).

Response to Arguments

Applicant's arguments with respect to claims 1-14 have been considered but are moot in view of the new ground(s) of rejection.

Regarding the maintained 112, 2nd rejections, Applicants' amendments have not overcome those rejections.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

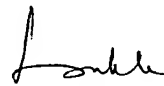
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
November 11, 2005


LONG V. LE
SUPERVISORY PATENT EXAMINER
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11/14/05